

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

UNITED STATES OF AMERICA
ex rel. John King and
Tammy Drummond, et al.,

Plaintiffs,

V.

SOLVAY S.A., et al.,

Defendants.

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CIVIL ACTION H-06-2662

ORDER

Pending before the court is a motion for partial summary judgment filed by relators John King and Tammy Drummond (the “Relators”). Dkt. 300. After considering the motion, the response, defendant Solvay Pharmaceuticals, Inc.’s (“SPI”) notice clarifying its invocation of certain affirmative defenses, and the applicable law, the court is of the opinion that the motion should be **GRANTED IN PART AND DENIED IN PART.**

I. BACKGROUND

This case is about alleged off-label promotion of three SPI drugs that Relators contend led to violations of the federal and state False Claims Act and alleged retaliation against Relators for complaining about the alleged False Claims Act violations. In its answer to the fifth amended complaint, SPI asserts twenty-five “affirmative and other defenses,” including contributory or comparative fault, waiver, estoppel, laches, unclean hands, failure to mitigate, superseding conduct of third parties, the learned intermediary doctrine, and the absence of damages. Dkt. 113 ¶¶ 5–6, 8–9, 17, 19. Relators now move for summary judgment on all of these defenses. Dkt. 300. SPI filed

a notice clarifying its invocation of certain affirmative defenses, in which it explains that it does not intend to assert some of the defenses highlighted in Relators' motion with regard to certain of Relators' claims. *See* Dkt. 328. SPI then filed a response to Relators' motion in which it argues that (1) Relators' motion is in actuality a motion to strike that is long overdue; and (2) even if the court were to entertain the motion as a motion for summary judgment, it should be denied. Dkt. 329. The court will consider each of the defenses *seriatim*.

II. LEGAL STANDARD

Relators move for summary judgment under Federal Rule of Civil Procedure 56, but SPI argues that the court should treat the motion as a motion to strike under Rule 12(f). Rule 12(f) gives the court authority to strike "an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter" from any pleading. Fed. R. Civ. P. 12(f). Motions to strike should be made either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading. *Id.* However, a court may strike an insufficient pleading on its own initiative at any time. *See* Fed. R. Civ. P. 12(f)(1); *Willaims v. Jader Fuel Co., Inc.*, 944 F.2d 1388, 1399 (7th Cir. 1991) (noting that courts have reasoned that they may "consider a motion to strike at any point in the case," considering the issue on their own accord even though "its attention was prompted by an untimely filed motion"). Motions to strike defenses are usually disfavored and infrequently granted because they are drastic remedies which are difficult to decide without a factual record. *Augustus v. Bd. of Pub. Instruction of Escambia Cnty., Fla.*, 306 F.2d 862, 868 (5th Cir. 1962). An affirmative defense is subject to the same pleading requirements as the complaint. *Woodfield v. Bowman*, 193 F.3d 354, 362 (5th Cir. 1999). Thus, a defendant must plead an affirmative defense with "enough specificity or factual particularity to give the plaintiff 'fair notice'

of the defense that is being advanced.” *Id.* A plaintiff is deemed to have fair notice when the defense is sufficiently described so that the plaintiff is not a victim of unfair surprise. *Home Ins. Co. v. Matthews*, 998 F.2d 305, 309 (5th Cir. 1993). In some cases, merely pleading the name of the affirmative defense will suffice. *Woodfield*, 193 F.3d at 362.

Some courts rule that a Rule 12(f) motion to strike is the proper procedure to strike an affirmative defense and that parties may not move for partial summary judgment on affirmative defenses. 10B Charles Alan Wright et al., *Federal Practice and Procedure* § 2737 (3d ed. 2004) (citing *Bernstein v. Universal Pictures, Inc.*, 379 F. Supp. 933 (D.C.N.Y. 1974) and *Uniroyal, Inc. v. Heller*, 65 F.R.D. 976 (D.C.N.Y. 1974)). Other courts allow partial summary judgment, as it “enable[s] the district court to enter an order indicating that the defense is no longer in controversy” and is not limited to the pleadings like a motion to strike. 5C Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1381 (3d ed. 2004); 10B Charles Alan Wright et al., *supra*, § 2737. The court finds the latter approach appropriate under the facts of this case.

Summary judgment is proper if “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); *see also Carrizales v. State Farm Lloyds*, 518 F.3d 343, 345 (5th Cir. 2008). The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; there must be an absence of any genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48, 106 S. Ct. 2505 (1986). An issue is “material” if its resolution could affect the outcome of the action. *Burrell v. Dr. Pepper/Seven Up Bottling Grp., Inc.*, 482 F.3d 408, 411 (5th Cir. 2007). “[A]nd a fact is genuinely in dispute only if

a reasonable jury could return a verdict for the non-moving party.” *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006).

The moving party bears the initial burden of informing the court of all evidence demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). Only when the moving party has discharged this initial burden does the burden shift to the non-moving party to demonstrate that there is a genuine issue of material fact. *Id.* at 322. If the moving party fails to meet this burden, then it is not entitled to a summary judgment, and no defense to the motion is required. *Id.* “For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial.” *Transamerica Ins. Co. v. Avenell*, 66 F.3d 715, 718–19 (5th Cir. 1995); *see also Celotex*, 477 U.S. at 323–25. To prevent summary judgment, “the non-moving party must come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (quoting Fed. R. Civ. P. 56(e)).

When considering a motion for summary judgment, the court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Envtl. Conservation Org. v. City of Dallas, Tex.*, 529 F.3d 519, 524 (5th Cir. 2008). The court must review all of the evidence in the record, but make no credibility determinations or weigh any evidence; disregard all evidence favorable to the moving party that the jury is not required to believe; and give credence to the evidence favoring the non-moving party as well as to the evidence supporting the moving party that is uncontradicted and unimpeached. *Moore v. Willis Ind. Sch.*

Dist., 233 F.3d 871, 874 (5th Cir. 2000). However, the non-movant cannot avoid summary judgment simply by presenting “conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation.” *TIG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). By the same token, the moving party will not meet its burden of proof based on conclusory “bald assertions of ultimate facts.” *Gossett v. Du-Ra-Kel Corp.*, 569 F.2d 869, 872 (5th Cir. 1978); *see also Galindo v. Precision Am. Corp.*, 754 F.2d 1212, 1221 (5th Cir. 1985).

III. ANALYSIS

A. Contributory or Comparative Fault

Relators argue that SPI’s defense that some contributory or comparative act of negligence or some failure to act by Relators bars their claims as a matter of law. Dkt. 300. In its notice clarifying its invocation of certain affirmative defenses, SPI states that it is not asserting the affirmative defense of contributory and comparative fault as to Relators’ federal *qui tam* and retaliation causes of action. Dkt. 328. SPI notes, however, that it intends to rely on this defense for the state-law claims and will rely on Relators’ admissions and other evidence to show that Relators’ misconduct was the actual cause of any financial harm they may have suffered as a result of their terminations. Dkt. 329. Since Relators have not moved for summary judgment on this defense as it relates to each state law claim, and SPI has abandoned the defense with regard to the federal claims, Relators’ motion for summary judgment on the contributory or comparative fault affirmative defense is **DENIED AS MOOT**.

B. Waiver and Estoppel

Relators move for summary judgment on SPI's affirmative defenses of waiver and estoppel, arguing that both are unavailable as a matter of law to defend against False Claims Act fraud claims. Dkt. 300. Relators assert that a violation of the rights of the United States cannot be waived by unauthorized acts of its agents and that estoppel is generally not available as a defense against the government. *Id.*

SPI notes first that Relators' motion does not address the state False Claims Act claims or their retaliation claims. Dkt. 329. SPI then argues that courts in this and other jurisdictions *have* denied summary judgment and motions to strike waiver as an affirmative defense in federal False Claims Act cases and that the U.S. Supreme Court has specifically declined to adopt a rule that "no estoppel will lie against the government." *Id.* (quoting *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414, 423, 110 S. Ct. 2465 (1990)). In *Richmond*, the U.S. Supreme Court noted that "estoppel might lie on some facts" and declined "to accept the Solicitor General's argument for an across-the-board no-estoppel rule." 496 U.S. at 426.

Relators cite *United States v. Cushman & Wakefield, Inc.*, and *Hicks v. Harris* in support of their contention that a violation of the rights of the United States may not be waived or ratified by the unauthorized acts of agents. *See* Dkt. 300 at 4 n.12. In *Cushman & Wakefield*, the district court in the Northern District of Texas was considering a motion to strike affirmative defenses. 275 F. Supp. 2d 763, 767 (N.D. Tex. 2002). The case was about whether Cushman & Wakefield was involved in a scheme to defraud the United States Postal System by avoiding payment of postage. *Id.* at 766. Cushman and Wakefield asserted waiver, estoppel, and ratification, among other affirmative defenses. *Id.* The United States moved to strike the affirmative defenses. *Id.* The court

ruled that estoppel is not available against the government if public money is at stake. *Id.* at 768. The court granted the motion to strike, agreeing with the United States that estoppel was not available because Cushman & Wakefield's actions had an "impact [on] the public fisc." *Id.* at 769.

In *Hicks*, the district court granted the government's motion for summary judgment, and the Fifth Circuit affirmed. 606 F.2d 65, 67 (5th Cir. 1979). The case involved the government's failure to cover defaulted students loans because the company that disbursed the loans did not receive a certificate of insurance from the Commissioner of Education prior to disbursing the loans. *Id.* at 66. The company claimed that employees at the Office of Guaranteed Student Loans "stamped the loan applications for approval after the beginning of the school term . . . and allegedly made statements approving [the company's] practice of disbursing loan money prior to the stamping of the loans." *Id.* The Fifth Circuit stated, "Although we believe that the government in this case has not turned square corners in its business dealings with its citizens, we reluctantly find that the applicable law controlling the use of waiver and estoppel against the government compels us to affirm." *Id.* at 67. The court reasoned that the government regulation relating to the Commissioner of Education's insuring of student loans did not allow the persons that the company stated waived the requirement to do so. *Id.*

While, as SPI points out, there may be *some* instances in which an estoppel or waiver defense can stand, SPI has failed to demonstrate that there is an issue of material fact as to whether the estoppel or waiver defense can stand in *this* case. Certainly, if the government reimbursed Medicaid prescriptions that were false claims as alleged in this case, then the outcome impacts the public fisc. SPI has pointed to no exceptions to this general rule or any argument as to why an exception should

apply in this case. Accordingly, Relators' motion for summary judgment on the affirmative defenses of waiver and estoppel is **GRANTED**.

C. Unclean Hands and Laches

Relators contend that it is black letter law that unclean hands and laches are not available as defenses against the government from federal False Claims Act fraud claims. Dkt. 300 at 5.

SPI states, first, that it did not intend to direct the defense of unclean hands to Relators' False Claims Act claims. Dkt 329 at 10. Because SPI has abandoned its unclean hands defense with regard to the False Claims Act claims, Relators' motion for summary judgment on the unclean hands defense with regard to the federal False Claims Act claim is **DENIED AS MOOT**.

With regard to laches, SPI argues that courts have recognized the potential viability of laches defenses in False Claims Act cases. *Id.* (citing *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton*, CIV. A. No. 02-5702, 2009 WL 4576097, at *6–7 (D.N.J. Dec. 1, 2009) and *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 646 (S.D. Ohio 2000), *aff'd* 302 F.3d 637 (6th Cir. 2002)). SPI asserts that, in this case, federal prosecutors were on notice of SPI's allegedly unlawful conduct for years, yet chose to take no action to prevent health care program beneficiaries from using SPI's products. SPI contends that this fact forms at least a predicate to argue laches in some circumstances. *Id.* SPI asserts that none of the authority cited by Relators deals with the wake of a multi-year investigation of allegedly ongoing criminal conduct. *Id.*

Relators cite four cases to support their motion for summary judgment on the laches claim: *Hernandez, Kroone & Associates v. United States*, *S.E.C. v. Follick*, *Cushman & Wakefield*, and *United States v. Manhattan-Westchester Medical Services*. In *Hernandez, Kroone & Associates*, the

Court of Federal Claims determined that neither the defense of unclean hands nor the defense of laches was available because the suit was instituted to vindicate a public interest. 95 Fed. Cl. 395 (Fed. Cl. 2010). In *S.E.C. v. Follick*, the district court in the Southern District of New York noted that the doctrine of unclean hands cannot “be invoked against a governmental agency which is attempting to enforce a congressional mandate in the public interest.” No. 00 Civ. 4385KMWGWG, 2002 WL 31833868, at *8 (S.D.N.Y. Dec. 18, 2002) (citations and quotation omitted). The doctrine can only be invoked, generally, if “the agency’s misconduct [is] so egregious and the resulting prejudice to the defendant rise[s] to a constitutional level.” *Id.* (citations and quotations omitted). Additionally, “courts have permitted the defense . . . where the alleged misconduct occurred during the investigation leading to the suit and the misconduct prejudiced the defendant in his defense of the action.” *Id.* In *Cushman & Wakefield*, the court held that the doctrine of unclean hands did not apply for the same reason estoppel and waiver could not be applied—because the case impacts the public interest and public fisc. 275 F. Supp. 2d at 774. Finally, in *Manhattan-Westchester Medical Services, P.C.*, a False Claims Act case relating to alleged false Medicare claims, the court stated that the “affirmative defenses of laches and unclean hands are . . . unavailable against the Government.” No. 06 Civ. 7905(WHP), 2008 WL 241079, at *4 (S.D.N.Y. Jan. 28, 2008).

SPI cites *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton* and *United States ex rel. Roby v. Boeing Co.* to support its argument that the court should allow the laches defense to stand with regard to the federal False Claims Act claim. In *Monahan*, the district court in the District of New Jersey denied a motion to strike an affirmative defense of laches. The United States was suing to recover Medicare losses, and the court reviewed cases in which courts had held that laches was an available defense in False Claims Act cases and determined that “the

unavailability of laches against the Government may not be as broad as the Government suggests.” 2009 WL 4576097, at *7. The court determined that in limited circumstances, laches may be applied against the government, and it was “not clearly apparent” that laches could not be applied under the facts of *Monahan*. *Id.* In *Roby*, the district court in the Southern District of Ohio denied a motion for summary judgment seeking dismissal of a laches affirmative defense. 100 F. Supp. 2d at 645. The court cited cases in which courts had found that laches could stand against the government, and then summarily denied the motion for summary judgment because there were genuine issues of material facts, without stating what facts made laches an appropriate defense.¹ *Id.* at 646.

Like with unclean hands, SPI has pointed to no reason why an exception to the general rule that laches will not lie against the government should be applied here. Accordingly, Relators’ motion for summary judgment on the laches defense is **GRANTED**.

D. Failure to Mitigate

Relators assert that the government does not have a duty to mitigate when fraud is alleged. Dkt. 300. Relators argue that requiring the United States to take steps to minimize SPI’s liability when the United States is a victim of fraud is antithetical to the purpose of the False Claims Act. *Id.* at 6.

SPI notes first that Relators do not contend that they had no duty to mitigate damages with regard to their retaliation claims. Dkt. 329 at 12. SPI argues that Relators’ argument focuses on

¹ In one of the cases cited by the *Roby* court, the court found that dismissal of affirmative defenses was premature, as the defendants had not had a chance to discover facts supporting their defenses. *See United States v. Hardage*, 116 F.R.D. 460, 467 (W.D. Okla. 1987). That is not an issue here. In the other case, the court was dealing with a challenge to a previously entered consent decree and the All Writs Act; it is not on point. *Bylinski v. City of Allen Park*, 169 F.3d 1001, 1002–03 (6th Cir. 1999).

False Claims Act claims based on fraud and not on the “kind of open and notorious conduct revealed to law enforcement officials for much of the time period at issue that Relators purport to place at issue in this litigation.” *Id.* SPI argues that since False Claims Act liability can be premised on a lower standard than fraud and because government knowledge has been held not to establish an absolute defense to liability, the premise that a victim of deception has no duty to mitigate does not attach cleanly to all varieties of False Claims Act liability. *Id.* SPI states that until Relators specify their theory of liability at trial, whether failure to mitigate can be a defense is uncertain. *Id.*

Relators cite *United States ex rel. Garrison v. Crown Roofing Servs., Inc.*, and *Toepleman v. United States*, in support of their argument that the Government had no duty to mitigate. In *Garrison*, Judge Werlein found that the “Government has no duty to mitigate damages where fraud is alleged.” No. CIV. A. H-07-1018, 2011 WL 4914971, at *1 (S.D. Tex. Oct. 14, 2011). *Garrison* was a *qui tam* case relating to a contract to repair the roof at NASA’s Johnson Space Center. *United States ex rel. Garrison v. Crown Roofing Servs., Inc.*, No. CIV. A. H-07-1018, 2011 WL 1005062, at *1 (S.D. Tex. Mar. 16, 2011). Judge Werlein dismissed the defense with regard to the fraud claims asserted but noted that the defense arguably could be applicable to the breach of contract claims. *Garrison*, 2011 WL 4914971, at *2.

In *Toepleman*, the Government sold cotton at a loss after holding it for six years while attempting to negotiate a settlement in a False Claims Act case relating to fraud tainting the notes to the cotton. 263 F.2d at 700 (4th Cir. 1959). The market had fluctuated during that time, and the Government could have sold the cotton for a profit if it had acted sooner. *Id.* The case did not settle, and the Government requested that the court award its losses on the cotton as damages. *Id.* The trial court held that the loss was not due to the fraud that tainted the notes, as the loss resulting from

holding the cotton six years would have been the same even if the notes had not been tainted. *Id.* The Fourth Circuit overturned this ruling. *Id.* The Fourth Circuit disagreed with the trial judge because “[b]ut for the fraud the cotton would never have been the Government’s responsibility. Having by his fraud thrust this burden on the United States, the appellant cannot be exonerated by the failure of the Government to case it off at the most propitious time.” *Id.*

SPI cites the definition of “knowing” or “knowingly” as used in the federal False Claims Act to demonstrate that liability can be premised on a lower standard of scienter than fraud. Indeed, knowing conduct under the federal False Claims Act requires “no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(B). The court finds that this is all a level of degree, and the claims in the case cannot possibly be construed to not involve some degree of fraud. The cases cited by Relators are clear that the Government is under no duty to mitigate in fraud cases, and SPI has provided no issues that raise a question that this case should be treated differently. Relators’ motion for summary judgment on the failure to mitigate affirmative defense with regard to the federal False Claims Act claim is **GRANTED**.

E. Superseding Conduct of Third Parties

Relators request that the court dismiss SPI’s superseding conduct defense because SPI did not plead the defense with particularity. Dkt. 300 at 11. Under Federal Rule of Civil Procedure 9(b), a party “alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). SPI argues that there are many aspects of Relators’ claims which could have actually been caused by third parties who were not necessarily engaging in fraudulent conduct. Dkt. 329 at 14. SPI contends that it is therefore not required to plead the defense with particularity. *Id.* The court agrees that there could be instances in which the

superceding conduct of third parties caused Relators' damages, the superceding conduct was not fraudulent, and therefore SPI would not be required to plead the defense with particularity.² Relators motion for summary judgment on this defense is thus **DENIED**.

F. Learned Intermediary

The learned intermediary doctrine is a common-law rule that “applies particularly to the medical field and unavoidably unsafe products like prescription drugs, which, by law, cannot go from the manufacturer to the end user except through a prescribing physician.” *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 165 (Tex. 2012).

Under the doctrine, a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. . . . If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. Accordingly, the doctrine excuses a drug manufacturer “from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.”

Ackermann v. Wyeth Pharm., 526 F.3d 203, 207 (5th Cir. 2008) (quoting *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999)). The doctrine thus is ““used to show to whom a defendant, usually a prescription drug manufacturer, owes the duty to adequately warn.”” *Centocor, Inc.*, 372 S.W.3d at 165 (quoting, with approval, *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 93–94 (Tex. App.—Texarkana, no pet.)). It is *not* an affirmative defense. *Ackermann*, 526 F.3d at 207. Instead, the doctrine bars a plaintiff's claims “if she cannot show that the allegedly inadequate warning was a producing cause” of her injury. *Id.* at 209.

² SPI cannot, however, later contend that *fraudulent* conduct of third parties was the superceding cause, as this allegation would have had to be pleaded with particularity.

First, Relators contend that SPI cannot invoke the learned intermediary doctrine as a defense to their retaliation claims. Dkt. 300. SPI states that it did not intend to do so and has filed a notice clarifying its pleading. Dkt. 329. The motion as it relates to the assertion of the learned intermediary doctrine as a defense to Relators' retaliation claims is **DENIED AS MOOT**.

Relators next assert that the learned intermediary doctrine does not apply to False Claims Act claims. Dkt. 300 at 8. Moreover, Relators contend that SPI cannot rely on the learned intermediary doctrine because there is no causal connection between the warnings given by a prescribing physician and the False Claims Act violations. *Id.* SPI contends that the learned intermediary doctrine will play a significant role at trial because of the way Relators intend to prove their False Claims Act claims. Dkt. 329 at 16. SPI argues that since Relators do not intend to provide evidence of individual false claims resulting from prescriptions written by physicians who were influenced by unlawful means, and instead will rely on expert statistical analysis and extrapolation, Relators should be forced to account for the role of the learned intermediary as a matter of affirmative proof as required in Texas or as an affirmative defense. *Id.* SPI asserts that this is a "cornerstone of SPI's rebuttals to those inferences." *Id.*

Relators support their argument that the learned intermediary doctrine does not apply with a case out of the Eastern District of Pennsylvania, *United States ex rel. Spay v. CVS Caremark Corp.*, CIV.A. No. 09-4672, 2013 WL 1755214 (E.D. Pa. Apr. 24, 2013). In *Spay*, the judge was considering a motion to strike the defendants' affirmative defenses. 2013 WL 1755214, at *1. The plaintiffs alleged that the defendant pharmacies violated the False Claims Act by submitting false claims under Medicare Part D and falsely certifying to the Center for Medicaid and Medicare Services ("CMS") that the claims were truthful, accurate, and complete. *Id.* The court noted that

the defendants had not cited any cases in which the learned intermediary doctrine was used against the United States in a False Claims Act case. *Id.* at *12. Moreover, the only alleged victim in the case was the government, not consumers, and the alleged False Claims Act violation would have occurred prior to any learned intermediary having an opportunity to warn consumers about the drug. *Id.* The court thus found that the “learned intermediary doctrine would have no logical purpose or practical application” under the facts of that case. *Id.*

Here, similar to *Spay*, the alleged victim is the government, and SPI provides no cases in which the learned intermediary doctrine has been used against the government. SPI argues, however, that Relators should be forced to account for the role of the intermediary given their unique theory of liability. While the court is unclear exactly *how* the learned intermediary doctrine will be of use in this case, and whether it can be considered an affirmative defense to any of the state False Claims Act claims, it believes it is premature to preclude its use at this point. Accordingly, Relators’ motion for summary judgment on the learned intermediary defense as it relates to the federal and state False Claims Act claims is **DENIED** without prejudice to reassert at trial should it become evident the use of the doctrine is inappropriate as a matter of law.

G. Absence of Damages


Relators move to strike SPI’s affirmative defense that Relators’ claims are barred to the extent the United States has suffered no damages because False Claims Act liability can be imposed even in the absence of damages. Dkt. 300 at 9. SPI asserts that the point of this affirmative defense is to bar recovery of any actual or treble damages that Relators cannot prove. Dkt. 329 at 17. SPI argues that there is a question as to whether false claims were even submitted, so there is a question as to whether there are any actual damages. *Id.* at 18. SPI contends that striking its no damages

defense prior to a review of all the evidence is contrary to controlling law and inconsistent with a full adjudication of the essential elements necessary to support the claims in this case. *Id.* Like with the motion for summary judgment on the Learned Intermediary Doctrine, the court finds that it is premature to grant summary judgment on this defense. Accordingly, the motion for summary judgment with regard to the absence of damages defense is **DENIED**.

IV. CONCLUSION

Relators' motion for summary judgment on SPI's affirmative defenses is **GRANTED IN PART AND DENIED IN PART**. It is **DENIED AS MOOT** with regard to the contributory or comparative fault defense as it relates to the federal False Claims Act claim, the unclean hands defense as it relates to the federal False Claims Act claim, and the learned intermediary doctrine defense as it relates to the retaliation claims, as SPI has clarified that it does not intend to assert these defenses with regard to those claims. It is **GRANTED** with regard to the waiver and estoppel defenses, the laches defense, and the failure to mitigate defense, as these defenses relate to the federal False Claims Act claim. It is **DENIED** with regard to the Learned Intermediary Doctrine as it relates to the federal and state False Claims Act claims, and it is **DENIED** with regard to the absence of damages defense.

Signed at Houston, Texas on February 4, 2015.



Gray H. Miller
United States District Judge